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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,980	12/27/2000	Elaine Lee	8600-0010	6822

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EXAMINER
BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 09/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No. 09/749,980	Applicant(s) LEE, ELAINE	
	Examiner Jessica R Baxter	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *25-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24 and 31-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 4 is acknowledged. The traversal is on the ground(s) that the search for one group will reveal art for both groups. This is not found persuasive because the restricted claims would require a new search as to how the different compositions are administered.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. As stated in the last Office Action, the abstract of the disclosure is objected to because the abstract is too general and does not contain enough information. The abstract does not include the components of the composition nor does it include the methods that the composition will be utilized in. Correction is required. See MPEP § 608.01(b).

3. The amended abstract is noted and accepted. The objection to the abstract is withdrawn.

Claim Objections

4. Claims 2 and 33 are objected to because the list within the claim has been misnumbered, as stated in the last Office Action. Appropriate correction is required.

5. Claim 1 is objected to because of the following informalities: change "and a material" to --and an additional material--, as stated in the last Office Action. It is unclear that the material is in addition to the vaso-occlusive member. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or

> with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Amended claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claim 1 includes "liquid fibrin", the specification, as filed, does not support the addition of the term "liquid" before the term "fibrin" because the specification only discloses that the composition is a liquid and not the fibrin itself. The claims have been examined using the original claim 1, as filed.

8. Claim 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term biodegradable is not supported in the specification. The specification, as filed only discloses that the composition is absorbable. It is unclear whether by absorbable, the applicant also means biodegradable. It is insufficient to incorporate the teachings of biodegradability with a reference in the specification. Claimed subject matter must be specifically disclosed in the specification.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 31-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 31, it is unclear what is meant by "a vaso-occlusive composition a vaso-occlusive member and a particulate liquid embolic material." There appears to be a term missing after

composition. The examiner has assumed that the term missing is "comprising" and has examined the dependent claims accordingly.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-4, 11-14, 18-21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,980550 to Eder et al. Eder discloses a vaso-occlusive device as claimed. Referring to claims 1-4 and 18, Eder discloses a vaso-occlusive composition that includes a vaso-occlusive coil (column 3 lines 17-20), a thrombus-stabilizing molecule (column 6 lines 38-41), and a bioactive material in the form of cytokine VEGF (column 6 lines 38-48). Referring to claims 11-13, Eder discloses a device that has a bioactive material, a thrombus-stabilizing molecule or both the thrombus-stabilizing molecule and the bioactive material permanently bonded to the vaso-occlusive member (column 6 lines 38-48). Referring to claim 14, Eder also discloses a vaso-occlusive composition that has been plasma treated (column 3 lines 60-61). Referring to claims 19-21 and 24, Eder discloses a method to occlude an aneurysm by administering the vaso-occlusive composition (column7 lines19-23 and lines 48-59) by administering the bioactive material VEGF.

13. Claims 1, 5-6, 16, 19 and 22 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 6,096,052 to Callister et al. Callister discloses the claimed occluding device. Referring to claims 1, 5 and 6, Callister discloses a device that comprises a vaso-occlusive member and an additional material of copper (column 8 lines 20-28). Referring to claim 16, Callister discloses a

device that is microtextured by sandblasting (column 8 lines 13-15). Referring to claims 19 and 22, Callister also discloses a method that administers the composition including copper to occlude a vessel(see claims 33-42 and column 8 lines 25-28).

14. Claims 1 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,894,022 to Ji et al. Ji discloses the claimed vaso-occlusive composition. Ji discloses a matrix base (Column 2 lines38-42) that cross-links fibrin(column 11 lines 65-67) to form a microscopic mesh (column 2 lines 53-56).

15. Claims1, 7, 8, 11, 17, 19 and 23 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,800,507 to Schwartz. Schwartz discloses the claimed vaso-occlusive composition. Referring to claims 1, 7 and 8, Schwartz discloses a composition that includes a vaso-occlusive member (column 4 lines 64-67) and thrombus-stabilizing molecule Factor XIII (column 3 lines 43-44). Referring to claims 11 and 17, Schwartz discloses a composition that the material fibrin is adsorbed to the vaso-occlusive member (column 3 lines 60-64) and the vaso-occlusive member has a tie layer between the stent and the material fibrin (column3 line 60 - column 4 line 4). Referring to claims 19 and 23, Schwartz discloses a method that administers a vaso-occlusive composition including the thrombus-stabilizing molecule Factor XIII (column 3 lines 43-44) to an occluded vessel (column 4 line 64 - column 5 line 5).

16. Claims 31-36 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,888,546 to Ji et al.

Regarding claim 31, Ji discloses a vaso-occlusive composition comprising a vaso-occlusive member and a particulate liquid embolic material (see Column 2 lines 30-37, Column 3 lines 61-Column 4 line 18).

Regarding claim 32, Ji discloses that the particulate embolic material is selected from the group of consisting of microspheres, granules, and beads (see Column 2 line 64 –67, Column 3 lines 18-22).

Regarding claim 33, Ji discloses that the composition further comprises a bioactive material of DNA (see Column 4 line 65- Column 5 line 6, Column 5 lines 23-59).

Regarding claims 35 and 36, Ji discloses that the particulate liquid embolic material and the particulate material is biodegradable (see Column 4 lines 57-62, Column 9 lines 11-16).

Regarding claim 36, Ji discloses a method comprising administering the vaso-occlusive composition (see Column 3 line 61 – Column 4 line 3).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz '507. Schwartz discloses the claimed device except for the use of plasminogen activator inhibitor-1 (PAI-1) or α_2-antiplasmin as the thrombus-stabilizing molecule. It is well known that Factor XIII, PAI-1 and α_2-antiplasmin may all be utilized to prevent a thrombus from breaking up. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace Factor XIII (column 3 lines 47-48) with PAI-1 or α_2-antiplasmin, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

19. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz '507 in view of U.S. Patent No. 5,891,192 to Murayama et al. Schwartz discloses the claimed invention except for the vaso-occlusive member being subjected to ion implantation. Murayama teaches that ion implantation alters the surface properties of a metal implant such as thrombogenicity, endothelial cellular migration and adhesion, minimally increases the dimensions of the implant, and increases the fixation of a protein coating on the metal surface of the implant (see Column 3 lines 21-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the metal stent of Schwartz '507 to include the application of ion implantation in order to change the surface properties including thrombogenicity, endothelial cellular migration and adhesion, minimally increase the dimensions of the stent, and to increase the fixation of the protein on the surface of the metal stent.

Response to Arguments

20. Applicant's arguments filed July 1, 2002 have been fully considered but they are not persuasive.

21. Regarding Claims 1-4, 11-14, 18-21 and 24, applicant argues that Eder '550 discloses that there are three components to his invention instead of applicant's two components. Although applicant is correct in the fact that Eder has three components, applicant neglects to consider that his invention, as claimed, is not limited to two components only. The applicant's invention must include a minimum of a vaso-occluive member and a material, Eder discloses these two components. Therefore, the rejection of claims 1-4, 11-14, 18-21, and 24 is proper.

22. Regarding claims 1, 5, 6, 16, and 19, applicant argues that the invention of Callister et al. '052 is for use in the reproductive tract and not for occluding the vasculature. Callister discloses that his

device is not limited to the reproductive tract and may also be used in the vasculature (see Column 1 lines 37-49). Therefore, the rejection of claims 1, 5, 6, 16, and 19 is proper.

23. Regarding claims 1 and 16, applicant argues that Ji et al. '022 does not disclose the use of liquid fibrin. However, the applicant does not specifically disclose that fibrin is liquid fibrin. Applicant only specifies that a liquid composition comprising fibrin may be used. Therefore, fibrin suspended in a liquid meets this limitation. Applicant's argument that Ji discloses "an essentially sponge-like structure having a semisolid/semi-liquid or spongy texture." Since the composition that Ji claims is semisolid/semi-liquid, it is classified as both a liquid and a solid. Therefore, the composition is a liquid and the rejection of claims 1 and 16 is proper.

24. Regarding claims 1, 7, 8, 11, 17, 19 and 23, applicant argues that Schwartz '507 is not used as a vaso-occlusive composition. Schwartz clearly discloses that the stent may be used for many different applications including treating occlusions or aneurysms (see Column 4 line 64 – Column 5 line 5). Therefore, the rejection of claims 1, 7, 8, 11, 17, 19 and 23 is proper.

25. Regarding the rejection of claims 1 and 15 over Murayama '192, the applicant's argument is moot. New grounds for rejection have been stated.

26. Regarding claims 9 and 10, applicant argues that Schwartz '190 is not used as a vaso-occlusive composition. Examiner agrees with this point, but the examiner mistakenly cited the wrong Schwartz reference. The rejection should have been made using Schwartz '507.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz '507. Schwartz discloses the claimed device except for the use of plasminogen activator inhibitor-1 (PAI-1) or α_2-antiplasmin as the thrombus-stabilizing molecule. It is well known that Factor XIII, PAI-1 and α_2-antiplasmin may all be utilized to prevent a thrombus from breaking up. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made

to replace Factor XIII (column 3 lines 40-48) with PAI-1 or α_2-antiplasmin, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Regarding applicant's arguments, Schwartz '507 clearly discloses that the stent may be used for many different applications including treating occlusions or aneurysms (see Column 4 line 64 – Column 5 line 5). Regarding applicant's argument that "replacing both the stents (with vaso-occlusive devices) and Factor XIII (with PAI-1 or alpha2-antiplasmin) would result in a completely different composition having a completely different function than contemplated by Schwartz '190". However, since the reference that was intended to be used, Schwartz '507, does disclose that the composition can be used as a vaso-occlusive device, the rejection regarding claims 9 and 10 using Schwartz '507 is proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731

jrb
September 6, 2002

MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
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